UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Vince Chhabria, Judge

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff, vs. INTUITIVE SURGICAL, INC., Defendant.	No. C 21-03496-VC

San Francisco, California
Thursday, October 7, 2021

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THE CLERK: Now calling 21-CV-3496, Surgical Instrument Service Company, Inc. versus Intuitive Surgical, Inc.

Counsel for the Plaintiff, please state your appearance.

MR. MCCAULLEY (via Zoom): Good afternoon, your Honor. Richard McCaulley, and I have my partner, Joshua Vanhoven here on behalf of Plaintiff. And I apologize, your Honor. I have a medical issue that kept me from tying a tie, and despite my -- my family's best efforts, I think I'm better off open neck for today.

THE COURT: No worries.

MR. MCCAULLEY: Thank you.

MR. CORRIGAN (via Zoom): Hi, your Honor. This is Jeff Corrigan. I represent the Hospital Plaintiffs, and while this is not our motion today, we are a related case, and counsel for the Defendants have said that they motion that they're going to file against us will be very similar to this one. So I thought I'd come on and just monitor goings on in case it sort of bleeds into our case somehow.

THE COURT: Okay.

THE CLERK: For the Defendant?

MS. LENT (via Zoom): Good afternoon, your Honor. Karen Lent from Skadden on behalf of Intuitive.

THE COURT: Good afternoon.

Okay. So, I would be happy to talk a little bit about the tying issue. I don't need to talk about the market definition issue. I don't want to hear any argument about that, but why don't we start with the question that I asked you the other day or maybe it was last night. I don't remember any more.

It seems to me that the -- that -- that PhotoMedex is irreconcilable with the Supreme Court's decision in Palm Wonderful, and so PhotoMedex is no longer good law, and if you apply -- if you take the approach taken by the Supreme Court in Palm Wonderful, you would say that this claim does not need to be dismissed based on preclusion by the FDCA.

So why am I wrong about that?

MS. LENT: Thank you, your Honor. Would you like me to address that?

THE COURT: Yes, please.

MS. LENT: Okay. PhotoMedex we don't believe has been effectively overruled by Palm Wonderful. Palm Wonderful held that the FDCA didn't categorically preclude all Lanham Act claims, but it did preserve the possibility that some Lanham Act claims might be precluded by the FDC.

THE COURT: No, but -- but the Ninth Circuit's --

the foundation on which the Ninth Circuit's ruling rested in Palm Wonderful was PhotoMedex, right? I mean, the Ninth Circuit said in its ruling in Palm Wonderful, our precedent, that is, PhotoMedex, requires us to conclude that this claim is precluded by the FDCA. And then the Supreme Court says, No, no. You've got it all wrong. You -- you approached this question completely incorrectly. And so how could -- I don't understand how you could argue with a straight face that there's not an irreconcilable difference -- an irreconcilable conflict between PhotoMedex and the Supreme Court's ruling in Palm Wonderful.

MS. LENT: Well, I think what the Supreme Court was holding was that the -- the circumstances in Palm Wonderful didn't require a finding of preclusion and that --

THE COURT: No. What the Supreme Court said in Palm Wonderful is that, you know, the Ninth Circuit took the completely wrong approach. The Ninth Circuit assumed that there's this -- applied this presumption in favor of FDCA preclusion of Lanham Act claim and assumed that anything that a court does in a Lanham Act claim that constitutes a pronouncement on, you know, whether something is lawful under the FDCA is -- is inappropriate. And so any Lanham Act claim that requires the Court to do that is precluded, and that was completely wrong. The two statutes operate together. One gives a competitor the ability to sort of

protect itself, and the other gives the FDA the ability to enforce the FDCA. And if you take that approach to our case right now, I think you lose, for the same reason -- for similar reasons to why they -- they lost -- the Defendant lost in Palm Wonderful. I mean, I don't -- and I think that if you apply the approach in Palm Wonderful, PhotoMedex has to come out the other way. I don't understand how PhotoMedex could have come out the same way with the Supreme Court's ruling in Palm Wonderful hanging over its head.

Can you explain how PhotoMedex could have come out the same way?

MS. LENT: Yes, because what Palm Wonderful was saying, the Court was saying there, was that the Lanham Act claims in Palm didn't require any court to delve into the meaning or the impact or the enforcement of FDA regulations. Those were two separate issues.

THE COURT: Can you show me the -- show me the language that you're referring to in Palm Wonderful.

MS. LENT: I'm on page 2231, and this is a syllabus, but I'm just looking at it.

THE COURT: Yeah, let's not look at the syllabus. Let's look at the actual case.

MS. LENT: I'm trying to find the same place that is in the -- the language that I'm looking at is that neither Lanham Act nor the FDCA forbids or limits Lanham Act

claims challenging labels that are regulated by the FDCA. And so there's no conflict there.

THE COURT: Right. But, I mean --

MS. LENT: And other courts have held that under circumstances where there is --

THE COURT: Show me the -- show me the language in Palm Wonderful that you think would support the Ninth Circuit's prior ruling in PhotoMedex.

MS. LENT: So, on 2239, it says under other types of labels regulated by the FDA, such as drug labels, it would appear --

THE COURT: Wait. Hold on. Let me -- let me make sure I'm at the -- we're at the same place. With the -- which paragraph are you on, the one that says holding at the -- the one that begins, "A holding at the FDCA"?

MS. LENT: Yes, yes.

THE COURT: Okay. Where are you?

MS. LENT: So I'm -- the fifth line down that starts -- the sentence starts "Unlike other types of labels."

THE COURT: Okay.

MS. LENT: "Unlike other types of labels regulated by the FDA such as drug labels, it would appear the FDA does not preapprove food and beverage labels

under its regulations and, instead, relies on enforcement actions, warning letters and other measures."

THE COURT: But how does that help the Ninth Circuit's decision in PhotoMedex or how does that help you?

MS. LENT: Well, that helps us because the FDA does regulate clearance of medical devices under 510(k), whereas in this case, they were saying that the types of labels that were at issue here at not regulated by the FDA.

THE COURT: But they don't regulate -- I mean, the FDA doesn't regulate what you are saying when your client is saying to hospitals. I mean, the FDA doesn't even come close to regulating what your client is saying to hospitals, right?

MS. LENT: But an adjudication of what -- whether what our client is saying to hospitals is false requires interpretation of the FDCA.

THE COURT: Well, that's true in the Palm Wonderful case too, isn't it? I mean --

MS. LENT: No.

THE COURT: Why not? Why not?

MS. LENT: It's not, because it's not a question of whether the FDA would have allowed that label. That's not what the question was in Palm Wonderful.

THE COURT: No. I mean, in the food labeling

cases, if the FDCA would allow the statement, you can't pursue a -- you can't pursue a false advertising claim under state law. It's preempted, right? And you -- you -- the -- I mean, what the -- what Palm Wonderful says is -- at least as far as I read it, is, Look, yes, the FDCA has -- the FDA has authority over this, right. But the FDA does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely on certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of the agency rule makers and regulators. Lanham Act suits draw on this market expertise by empowering private parties to sue competitors to protect their interest on a case-by-case basis. The FDA does not necessarily pursue enforcement measures regarding all objectionable labels. And so if the Lanham Act claims were to be precluded, then commercial interests and indirectly, the public at large, could be left with less effective protection in the food and beverage labeling realm than many other less regulated industries.

I mean, why don't all of those concepts apply to show that the Ninth Circuit was -- that -- that PhotoMedex is no longer good law and that you cannot get a ruling that the Lanham Act claim is -- is precluded here by the FDCA?

MS. LENT: Because the claim in Palm was that the label was misleading to consumers, and the label can be misleading to consumers about whether it is pomegranate juice when it only contains less than a percentage of pomegranate juice without knowing --

THE COURT: But if the FDCA -- if the FDCA allows the label, if the label is permissible under the FDCA, then it can't be misleading, right, because the FDCA prevents misleading labeling, right?

MS. LENT: Well, I don't think that's -- I don't think that's what the Court was saying. The Court was saying we can decide whether this is misleading to consumers, regardless of whether it would be acceptable under the FDCA.

THE COURT: Where does it say that in Palm Wonderful? I just want to make sure you have a chance to show me where it says that, because I didn't see anything like that in Palm Wonderful. Now, I might have missed it, but now is your chance to show me where that language is.

MS. LENT: So, your Honor, I think you're raising an issue about the Palm -- about whether there was a violation of the FDCA or whether the FDA would allow the label that wasn't expressly addressed in Palm Wonderful. I mean, the Court just said that the claim --

THE COURT: But the -- that's why the Ninth

Circuit ruled in favor of the Defendants in Palm Wonderful, right? And the Ninth Circuit says, no, this -- a court ruling on this would infringe on the FDCA -- FDA's authority to decide whether this is misleading or not. And the Supreme Court says, No, no, no. You analyzed that totally wrong.

MS. LENT: But that's not what the Plaintiff's argument was in Palm Wonderful. They weren't saying that the FDA said that the label was approved. They were just saying, Well, the FDA regulates labeling on beverages.

THE COURT: Right.

MS. LENT: And so it has to be --

THE COURT: If the --

MS. LENT: -- precluded.

THE COURT: Right. And the Defendants were saying if -- and the Ninth Circuit said if the Court were to hold under the Lanham Act that this was misleading, that would interfere with the FDA's prerogative because it's for the FDA to decide whether it's misleading under the FDC -- FDCA, right. And the Supreme Court said, No, you totally got it wrong.

And so you're making the same argument here to -- in support of a ruling that the Lanham Act claim is precluded. You're making the same argument that the Supreme Court said the Ninth Circuit got all wrong, and it was -- that was the

approach that the Ninth Circuit took in Photo -- whatever it was called, PhotoMedex?

MS. LENT: PhotoMedex. I don't think we are making the same argument, your Honor, because in Palm Wonderful, the FDA hadn't done anything, whereas, in our case, this is about Intuitive's 510(k) approval and the scope of that approval, and the FDA has done something with respect to the 510 clearance. It has granted it. And whether the adulterated devices that SIS would like to offer are -- are allowed or not or would -- would be contrary to the 510(k) clearance is a different issue, and there are a number of courts that have said that the Palm Wonderful court left open this issue of when the FDA has affirmatively acted. There are --

THE COURT: But so --

MS. LENT: There are --

THE COURT: So --

MS. LENT: There are a number -- I'm sorry.

THE COURT: Tell -- tell me about those cases.

MS. LENT: So --

THE COURT: What are -- give me the cites is what I mean to say.

MS. LENT: Sure. So one case that we've already cited in our briefing is JHP Pharmaceuticals, and that's 52 F.Sup.3d, 992. It's a Central District of California case

from 2014, and that case extensively analyzed the effect of Palm on PhotoMedex. In fact, the Court there stayed the case pending the Supreme Court decision in Palm, and the JHP court concluded that the Lanham Act claim was precluded in the absence of a clear statement by the FDA. So -- so there, you know, it was -- if someone was saying that the FDA approved something and the FDA hadn't approved something, then you could have a Lanham Act claim, but otherwise, you could not, and it would be precluded because the --

THE COURT: That sounds like an artificially -- I mean, I haven't read the case, and I'll read it, but it sounds like an artificially narrow reading of Palm Wonderful. I mean, that's -- Palm Wonderful didn't say that, you know, the Lanham Act claims are precluded unless -- unless the Defendant said some -- said that the FDA said something that it didn't say.

MS. LENT: Well --

THE COURT: But, anyway, what else? I want to make sure to read the other cases that you're referring to.

MS. LENT: So there's a case called Catheter Connections v. Iverna Medical Corporation, and the citation is 2014 Westlaw 3536573, and that's from the District of Utah in 2014, and that case directly addresses the issue we have here. In that case, the Plaintiff alleged that the

Defendant engaged in false advertising, in violation of the Lanham Act when it represented that its product did not need 510(k) clearance, and the Catheter Connections court held that the claim was precluded by the FDCA even --

THE COURT: And that was a post -- that was a post-Palm Wonderful case?

MS. LENT: Post-Palm Wonderful. It considered Palm Wonderful, and it said the -- the rationale of PhotoMedex survived this part of Palm Wonderful or this -- this rational of PhotoMedex survived Palm Wonderful because the -- the Plaintiff was essentially arguing that the Defendant hadn't complied with Section 510(k) of the FDCA. It's the -- it's very similar to the situation we have here. And those courts, the JHP Pharmaceuticals court and the Catheter Connections court essentially said that the Lanham Act claim could be precluded if it relies on the Court to interpret and apply the FDCA.

There's a difference between what the --

THE COURT: But the Court was being -- but the court was being relied on to effectively interpret the FDCA in the Palm Wonderful case, right, because --

MS. LENT: I don't agree with that, your Honor. I don't agree with that. I think that the Plaintiffs claimed that the -- that the advertisement was misleading, that the label was misleading, and the Defendants came in and said --

and they waived their hands around, and they said, Oh, labels, labels, they are regulated by the FDCA, and the Court said, That's not enough. You can't say that. These two statutes can exist in harmony, and it is possible to do your consumer survey and say, This label is misleading. I thought this label meant that the juice was pomegranate juice, and there's barely any in it, and you could win on your Lanham Act claim under that --

THE COURT: But -- but what if the -- but then that -- the decision of whether that assertion about pomegranate juice is a decision that the FDA can make, right, or the FDA can decide under the FDCA whether that assertion is misleading or not. So you have a court issuing a ruling about whether a label is misleading when the FDA has the authority to decide whether the label is misleading, and you have the Supreme Court saying that's not a problem.

MS. LENT: But it said that's not a problem and the language I read to you because the FDA doesn't preapprove food and beverage labels. In this instance, the FDA preapproves the marketing of medical devices under either 510(k) or, you know, a premarket application. So that's the difference, and that's why it matters that the Supreme Court said the different here is that there's no preapproval process for labels. The FDA hasn't spoken and preapproved this label. This is just a label that exists.

Sure, the FDA could come in and enforce the fact that this label is misleading, but it doesn't have to do that. And so there's no tension between these Plaintiffs saying this is false and misleading advertisement and the fact that the FDA could potentially bring a claim like that, but they don't need to exist in tension.

THE COURT: Okay. And what claim would the FDA bring against you for asserting to hospitals that the -- that the Plaintiff's actions are outside the scope of FDA approval?

MS. LENT: I don't think that the FDA would bring a claim against us saying that --

THE COURT: So this is conduct -- so -- so this is conduct that you've engaged in that is covered neither by the Lanham Act nor the FDCA?

MS. LENT: No, not --

THE COURT: Because -- because in the -- in the -- at least in the PhotoMedex case, if I remember correctly, and in the Palm Wonderful case, right, the conduct that the Defendant engaged in, the argument was, Hey, this conduct that the Defendant engaged in is covered by the FDCA, and the FDA could go in and enforce the FDCA as it relates to this conduct if it wanted to. Here the Plaintiffs are alleging that you've engaged in certain conduct, and the FDA -- I think the FDA could not take any sort of enforcement

action against you for the assertions that you made about the Plaintiffs, but you're saying that, nonetheless, the -- the Plaintiffs cannot bring a Lanham Act claim against you for that conduct either. So neither statute covers the conduct that you've been -- the misconduct that you've been accused of engaging in.

MS. LENT: Under the case law, your Honor, that follows -- that predates and follows Palm, when the analysis would require interpreting the FDCA in a -- and involve interpreting an action that the FDA has taken, such as the granting 510(k) clearance to -- into EndoWrist products, the claim is precluded.

THE COURT: Okay. I -- I will go back and read your cases to make sure I'm not missing something. So, JHP Pharmaceuticals you said?

MS. LENT: Yes.

THE COURT: And Catheter Connections. Anything else?

MS. LENT: Yeah. I would also point you to the -- let me see. I would also point you to Excela Pharma Sciences v. Sandos.

THE COURT: How do you spell Exela?

MS. LENT: E-X-E-L-A.

THE COURT: Okay.

MS. LENT: And that is --

THE COURT: And what's the cite?

MS. LENT: 486 F.Supp.3d., 1001, and Azurity, A-Z-U-R-I-T-Y, Pharmaceuticals v. Edge, and the cite for that is 2021 U.S. District Lexis 95300.

And -- and then just finally, your Honor, I would point you to -- to Thermolife v. Gaspari Nutrition, which is a Ninth Circuit case, 648 F. Appendix 609. And in that case, the Ninth Circuit expressly declined to determine whether PhotoMedex was --

THE COURT: Yeah, but it -- but it wasn't -- wasn't presented to them, right?

MS. LENT: It was presented to them, and they --

THE COURT: No, because they said even under PhotoMedex, the Plaintiff wins here, right. So it doesn't matter.

MS. LENT: Right, but they distinguished the circumstance, and so I think it's -- it's instructive to the analysis that we've been talking about today.

THE COURT: Okay. Thanks. Do the Plaintiffs briefly want to respond to anything?

MR. MCCAULLEY: Just briefly, your Honor. We do agree that Palm Wonderful is -- is broad and if it doesn't completely overrule PhotoMedex, gives it very little room to breathe.

We note that Judge Praegerson in the JHP case, that --

I haven't read many of the cases that I've heard of for the first time today, but I do know that in the THP (sic) case, I think there's some instructive language that relates to this case. Judge Praegerson there found that not being asked to usurp, this isn't a Lanham Act claim that is masquerading as an enforcement action or vice versa. When we're simply being asked to interpret what the FDA has done, certainly the Court can and has the power to do that under the Lanham Act. And that's the nature of our claim here, your Honor. The FDA has made an approval of the EndoWrist products, and we contend that they misrepresented the nature of that approval. That's the nature of our Lanham Act claim.

So, even if there is some room, if there is some oxygen for the PhotoMedex case, it wouldn't apply in this case. That's all, your Honor.

THE COURT: Okay. Let me ask -- Ms. Lent, let me ask you about the tying issue, and I don't want to take too much time on it, but I will say that I've read the Florida -- the district -- Florida District Court ruling, and I've read your arguments, and I guess I'm just not -- I'm having a hard time getting through my brain why we should conceive of this claim as a refusal to deal claim rather than a tying claim. I mean, it kind of seemed like the District Court in Florida was just sort of waving a wand and saying, I deem

this a refusal to deal claim, but I -- I didn't -- it doesn't make a logical sense to me why you would conceive of this as a refusal to deal claim. I mean, what they're alleging is that, you know, there is this -- you know, that there's this demand for this competitor's product, and the Defendant has altered their product to -- to prevent that demand from being realized, and -- and to ensure that only the Defendant's tied product can be used with the primary product, and I just don't understand why we should -- it seems like you're asking to just pronounce it a refusal to deal claim when that's really not what it is. That's not what they're arguing. That's not what they're alleging.

MS. LENT: Well, as an initial matter, your Honor, I think your question assumes that there are two separate products here, and we are --

THE COURT: And I believe that for the purposes of the pleadings stage, there are two separate markets.

MS. LENT: Okay.

THE COURT: And I don't need to hear argument on that. That will be the ruling on the motion to dismiss.

MS. LENT: Okay. Well -- okay. Well, this is not a product redesign like the cases that Plaintiffs have cited. The EndoWrists have always been designed so that they contain a usage counter. That's what was approved by the FDA, and customers have always known from the start when

Intuitive started selling Da Vinci systems in the early 2000's that the EndoWrist were limited-use instruments.

THE COURT: But why -- I just -- I read that argument, but I guess I don't understand why that matters, because their claim is that -- I think they would agree with what you -- everything you just said, right, and they would say, but what we are alleging is that this was always designed to have a, you know, use limit. A market developed for a service that allowed that use limit to be exceeded, and that's a -- there's a market for that, and the -- the -- the -- the Defendant made a design change to snuff that out, and the only purpose was to snuff that out, and the only purpose of it was anti-competitive.

Now, I can imagine in my own mind all sorts of legitimate reasons why that design change might have been made, and I'm -- I will say that I'm sort of at least initially somewhat skeptical of the claim, but that's not the test at the motion to dismiss stage. You know, they -- what they have alleged is that there was this demand for this service that developed. You just changed the design for the sole purpose of snuffing it out, and it has no -- it has -- that was the -- it was only that anti-competitive reason that you made the change. And I -- I'm sort of skeptical of it, but it's not implausible or at least I believe that the design change was made to prevent people

from circumventing the use limit, but I'm sort of suspecting that there may have been legitimate reasons to do that, but that is for the motion -- for the summary judgment stage, right? That's not for this stage, and I don't -- that's what they allege, and I don't understand why we would just sort of pronounce that this is a refusal to deal claim. I don't even understand the argument that it's a refusal to deal claim. It's not. It's a -- it's a tying claim, and it's a -- you know, and -- and at the pleading stage, I think we have to accept that. So I guess I don't really understand why the District Court in Florida ruled the way that it did, and I don't understand how I can sort of re-conceptualize their claim in the way you're asking me to do here.

MS. LENT: So -- so the reason why I say it's not a design change is because there's always been a usage counter, and that's always been a part of the instrument. The fact that the usage counter was done with one chip versus another chip later, that's -- that's what -- what we're disputing is an actual design change. The instrument was always designed to prevent people from using it past 10 uses, and that has not changed from the S and SI instruments to the X and XI instruments. That's the design. There's a different technology. There's a different chip in the device because technology changes over time, but that's not

change to the design of the EndoWrist in terms of preventing it from being used more than usually 10 times.

The other point that I want to make, your Honor, in response to your -- your question about, you know, why -- why is -- why isn't this something that was done intentionally to prevent or for the sole purpose of preventing SIS and others like it to -- to do what they're doing, the timing is all wrong, right. And if you look at the complaint, it says that the X and XI robot and instruments were introduced in 2014, right. No one was out there trying to reset the usage counters on any EndoWrist until at least 2018, and certainly SIS hasn't alleged that they were engaged in some process of trying to reset usage counters on EndoWrist before 2014. They weren't. So there was -- so the premise that -- that the technology that supports the usage counter was changed because it was an attempt to prevent this market that had sprung up to repair EndoWrist, that's not supported -- that's not alleged in the complaint anywhere. Actually, the complaint alleges a different timeline that, again, the -- the change that the Plaintiffs are claiming was made was made in 2014.

THE COURT: Okay.

MS. LENT: So I --

THE COURT: That's not a -- that's not a point that I had zeroed in on. So -- so do you want to -- the

Plaintiffs want to start by addressing that point?

MR. MCCAULLEY: Sure. Thank you, your Honor. We said it's in response to SIS and others, and seeing where the market was going, at the pleadings stage --

THE COURT: Well, but if SIS didn't start doing it until 2019 -- 2018 --

MR. MCCAULLEY: They did not, but our understanding, your Honor, is people are doing it around --

THE COURT: The change was made in 2014. Do you -- is that accurate? Is that what your complaint alleges, that the change was made in 2014 and you didn't start doing it until 2018?

MR. MCCAULLEY: I believe that's right, your Honor. But I -- I do believe the evidence that will develop at trial will show that others around the world were doing it as of 2014. That's what we understand.

THE COURT: Well, but -- but the question is not what the evidence will show. It's -- the question is what you've pled. So if you've pled that they -- they did this to stop SIS and others from -- from changing the counter and if SIS wasn't doing it then, isn't that -- I mean, haven't -- isn't that a problem? I mean, don't you need to -- I mean, it sounds like what you're saying to me is we need leave to amend -- I -- like I said, I haven't looked at this. I haven't looked at this issue. I haven't -- I

haven't zeroed in on this, but it sounds like what you may be saying is we said they did this to stop SIS and others from changing the counter. We alleged that incorrectly because the timing is all wrong. We need to go back and fix it to explain what -- to give a better explanation of what the anti-competitive purpose was. I mean, is that what you're saying or --

MR. MCCAULLEY: We certainly would be happy to replead it, your Honor, if that's necessary. I think the indirect response to others and then seeing where the market was headed, which ultimately was occupied by SIS, but it is accurate to say that SIS was not doing this as of 2014. That's accurate.

THE COURT: Okay. All right. What about the -- what about the larger point about whether this should be construed as a -- as refusal to deal with --

MR. MCCAULLEY: I'm sorry, your Honor. I didn't hear you.

THE COURT: What about the larger point that Ms. Lent makes about the -- that this should be construed as a refusal to deal claim because it wasn't really a change to the -- to the technoloy? It was just -- the product was always designed to, you know, exclude more than 10 uses.

MR. MCCAULLEY: The product was always designed to exclude more than 10 uses. And, as we've alleged I believe

in paragraphs 107 and 108 and 74, the usage counter has no impact on the function of the device and that there's no pro-competitive benefit to beefing up the security on that chip. It only had an anti-competitive effect. So it wasn't that the function was changed. The level of the security and the nature of the security on the chip was changed, for no -- no reason that benefitted consumers, no reason that benefitted Mr. Corrigan's clients, simply to keep -- to suppress competition, to prevent people from servicing the EndoWrist and meeting the demand that existed and exists in the market for those. And so there's no pre-competitive reason for increasing and changing the security. So what I'll -- the usage counter, we're not disputing that they're entitled to have the usage counter. We're just saying the change to the security in the chip had no pro-competitive reason and that it had an anti-competitive effect by --

THE COURT: When you say there -- you're not disputing that they're entitled to have the usage counter, you're saying that you're not disputing that they have the -- they're entitled to configure it so that it won't work after 10 uses?

MR. MCCAULLEY: They're entitled to have the configuration that they had. There's no pro-competitive reason to change the level of security. That's what we're contending.

THE COURT: Okay.

MS. LENT: Your Honor, may I --

THE COURT: Can I just --

MS. LENT: I'm sorry.

THE COURT: Well, I just wanted to ask Mr. McCauley while I had him that I wanted -- I have to say, I mean, this -- let's take a step back from the motion to dismiss for a second and -- or maybe not take a step back from the motion to dismiss. Let's talk about plausibility. We have this company that has this device and sells this device, and it seems to me as a matter of common sense that, you know, and it's been approved by the FDA, and the -- the company has to be very very concerned about whether this device that it's sending out to hospitals is going to malfunction, and the company has to be very very concerned that if other, you know, companies are opening up the device and messing with it and changing the number of times it's able to be used, that you're -- you're really increasing the risk of these products malfunctioning, and obviously it's in the -- it's in the company's interest to minimize that risk, and it's in the patient's interest for that risk to be minimized.

Just sort of as a matter of logic, doesn't it seem reasonable for the company to advocate for hospitals not to allow other companies to come in and override the settings

on the device that -- that the Defendant is selling? I mean, I know we're at the motion to dismiss stage, and I'm sort of -- maybe you get past the motion to dismiss stage because, you know, the question that I'm asking relates to summary judgment, but when we get to summary judgment, I mean, aren't you going to lose your -- this case? I mean, it -- I have a hard time imagining how a company doesn't have -- a company like the Defendant doesn't have the ability to advocate in the strongest possible terms that you shouldn't be allowing, you know, third parties to come in and override the settings of our device -- of our devices, which are designed to minimize, you know, risk to patients.

MR. MCCAULLEY: I think that's tied up -- I'm sorry, your Honor. Am I interrupting? Are you --

THE COURT: No, no. I was done.

MR. MCCAULLEY: I think, your Honor, that will be tied in with how the limit of 10 uses was -- was set, are there legitimate safety concerns after a device has been used 10 times. Now, as I understand it, hospitals are required to -- to throw these devices away after 10 sterilizations. They haven't even been used once, when the approvals for these devices were based on -- based on standard surgical devices that are reused hundreds if not thousands of times, and this is what our clients heard from hospitals. And so the maintenance of the limitation and

providing security and preventing competition in inspecting these devices, repairing them, and putting them back on the market ties in with the entire claim.

So I think we'll hear a lot of evidence, and we'll develop a lot of evidence about what -- how this limitation of 10 uses was set and whether it's a legitimate safety concern or a mechanism to drive up profits based on the very expensive prices of these replacement EndoWrists.

THE COURT: Okay. Ms. Lent, do you want to have the last word on any of this stuff briefly?

MS. LENT: Sure. I just wanted to go back to address Mr. McCauley's agreement that it's not -- that it's fine for Intuitive to put a usage counter in the instruments. So they're not --

THE COURT: Yeah, I was -- I was sort of startled by that. So go ahead.

MS. LENT: Yeah. So there's not an anti-trust violation from using a usage counter. They -- what they want is for the usage counter to be simple enough so that they can hack into it, and I don't understand how that's an appropriate claim for relief.

THE COURT: But if it's --

MS. LENT: They're upset -- excuse me. They're upset because someone figured out how to hack into the first usage counter, but the usage counter in the new instrument

they haven't quite figured that out yet, but it's okay that it's there. It's just that it's too hard for them --

THE COURT: Yeah. I mean, I didn't -- I didn't -- I was surprised by that too, but was that in the complaint? I mean, was -- does the complaint say that it's okay that the usage counter is there?

MS. LENT: So the complaint doesn't challenge the usage counter as an anti-trust violation. And, your Honor, their business actually depends on there being a usage counter, because if the instrument is -- doesn't need to have its usage counter reset and a hospital's just going to continue to use it, despite the safety risks that Intuitive has identified, then no one's going to SIS in order to have a usage counter reset. So they need the usage counter to support their business model.

THE COURT: But they might still -- I mean, I guess that begs the question of how much money are they making on usage counter reset and how much money are they making on, you know, repairs and stuff.

MS. LENT: Yes. I think it's much less actually. And, you know, I know that that's not part of the pleadings in this case, but there's a reason why companies want to get into this business, and it's because sharpening the ends of scissors in laparoscopic instruments is not a profitable enterprise, but trying to reset a usage counter on a

sophisticated piece of equipment like an EndoWrist is something they can charge more money for.

MR. MCCAULLEY: Your Honor, if I -- oh, I'm sorry.

THE COURT: No, go ahead.

MR. MCCAULLEY: Well, I -- and I think it goes to the point -- and I -- I perhaps should not have shorthanded it by saying we're not objecting to the usage counter. The usage counter as set by Intuitive allows them to charge super competitive prices for products that are unnecessarily limited in the number of uses, and we certainly contest that.

We -- so I -- I hope I didn't make a vague or inaccurate statement that surprised everyone. I mean, we obviously are contesting the way that the intuitive products are configured, marketed, sold when there is a viable replacement market. That does not violate any FDA restrictions, and that provides significant value to the market.

Oh, I think we did plead in our complaint that we have -- are aware of safety data testing that was done to validate up to 50 uses, safe uses of the EndoWrist, and I'm sure it probably goes beyond that. That is in -- I'm not sure what paragraph it is, but I'm sure we can find it for you, your Honor, that --

THE COURT: Okay.

MR. MCCAULLEY: -- that --

THE COURT: Okay. I will -- I will -- I'll give all of this a little more thought and issue a ruling.

MR. CORRIGAN: Your Honor, if I might, since I -- I may justify my appearance here, if I might. Ms. Lent said something. She said that SIS needs a usage counter. Well, I will step in for the Hospitals and say certainly the Hospitals do not need a usage counter. As Mr. McCaulley pointed out before, Intuitive got these EndoWrists approved by likening them to laparoscopic surgical instruments. There's no use limit on the laparoscopic surgical instruments. So slapping a 10-use limit on --

THE COURT: Yeah, but the laparoscopic surgical instruments are not attached to a complicated robot.

MR. CORRIGAN: We're saying that the operative part is the scissors, is the scalpel. I mean, can you using a pair of scissors 10 times and having to throw it out? I mean, somebody in Intuitive --

THE COURT: I think that -- I think that's very question begging. I don't -- it doesn't seem relevant to why you might want to have a counter for the -- for the -- the parts that are attached to a complicated robot. But, in any event, I think we may have plenty of time to debate that as --

MR. CORRIGAN: Thank you, your Honor

THE COURT: -- as time goes on.

So, okay. I'll think more about this and look -- I want to in particular look more closely at the 24 -- 2014, 2018 issue, which I hadn't noticed, and -- and then I want to read your cases on the preclusion issue, the Palm Wonderful issue, and so it may take a little while, but I'll issue a ruling.

MS. LENT: Thank you, your Honor.

THE COURT: Thank you.

MR. MCCAULLEY: Thank you, your Honor.

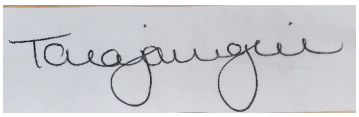
MR. CORRIGAN: Thank you, your Honor.

(Proceedings adjourned at 4:19 p.m.)

CERTIFICATE OF TRANSCRIBER

I certify that the foregoing is a true and correct transcript, to the best of my ability, of the above pages of the official electronic sound recording provided to me by the U.S. District Court, Northern District of California, of the proceedings taken on the date and time previously stated in the above matter.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to the action in which this hearing was taken; and, further, that I am not financially nor otherwise interested in the outcome of the action.



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